DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 6, 2014

PS Advanced Engineering
CD Feak
President
200 South Garfield Avenue, Suite 103
Alhambra, California 91801

Re: K133546
Trade/Device Name: StarLite-OM SL-8813
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: June 30, 2014
Received: June 30, 2014

Dear Feak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133546

Device Name
StarLite-OM SL-8813

Indications for Use *(Describe)*
SL-8813 is an Over The Counter (OTC) handheld device intended for in the treatment of full face wrinkles

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.08.04 15:17:58 -04'00'

510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92

1) General Information

Submitter: PS Advanced Engineering
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Alhambra, Calif.
91801

Contact Person: C D Feak
President
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Summary Preparation Date: 24 October 2013

2) Product Code = OHS

3) Product Names :

Device Common Name: Light Based Over The Counter Wrinkle Reduction

Device Model Number : SL88-13

Trade Names: StarLite-OM, Light Effects, Thibiant

Classification Name: Laser Instrument, Surgical Powered – General and Plastic Surgery – Class II, Gen 79-GEX

Although this device is not a Laser and is intended for Over The Counter use, the manufacturer believes this is the classification name which is most applicable and is the same classification as the LightStim (K120775), Trinity Wrinkle Reducer (K120560), Baby Quasar Plus (K130225) and StarLite-LM (K092460) devices.

Indications for Use: The SL8813 is an Over The Counter (OTC) handheld device intended for use in the treatment of full face wrinkles.

4) Predicate Devices

Primary: LightStim for Wrinkles (K120775), Trinity Wrinkle Reducer (K120560), Baby Quasar Plus (K130225)
Secondary: StarLite-LM (K092460)

Summary Descriptive Sections:

5) Device Description

SL-8813 is a handheld ergonomically designed ABS plastic housed device with a locking Medical Grade Stainless Steel retainer holding in place a Medical Grade USP Class polycarbonate lens from which high spectral purity LED light in 4 (four) specific wavelengths is emitted. By design the optical output has a high degree of homogenous light distribution. The output wavelengths are actuated via a simple on-off swipe button and are in the visible Red and the Infrared spectrum. SL8813 is powered by a built in (non user accessible) Lithium Ion Battery which can be charged as required via a supplied UL listed AC/DC wall mounted unit. Treatment time for light outputs is controlled by the operator as per Treatment Protocols listed in User Documentation. Audible announcement is provided to the user for timing intervals of treatments and is so noted in User Documentation.

6) Substantial equivalence in Indications for Use

The SL-8813 and the Predicate devices are hand held LED emitting devices intended for Over The Counter patient usage to specifically reduce facial wrinkles.

The target patient population for SL-8813 is identical to the population of the predicate devices.

SL-8813 and the Primary Predicate devices claim to emit identical frequencies or wavelengths of LED light energy with all claiming to meet 65mW/cm2 fluence levels with specific irradiance level distributions for the wavelengths and using the same treatment methods for the same treatment areas.

All devices emit in the Red and Infrared region within the “human safe” EC 62471 AND EU DIRECTIVE 2006/25/EC classification.

7) Performance Data compliant to Predicate Devices

a) Evaluation Testing:

1) SL-8813 electro-optical performance verification of LED power densities (mW/Cm2), pattern homogenous-ness and electrical performance were conducted referencing Table 1 International Standards.
2) Safety and essential performance designed for and validated referencing Table 1 International Standards.
3) SL-8813 optical energy output fluences are set in each specific wavelength to minimally meet the claimed fluence levels in each of the specific wavelengths as the Primary Predicate devices

Based on analysis of the performance, indications for use, user demographic base, safety and effectiveness characteristics for SL-8813, PS Advanced Engineering (PSAE) believes that the SL-8813 meets all criteria claimed by the previously approved Primary Predicate Devices.

8) Performance Data compliant to Secondary K092460

Based on an identical physical design and fitment as well as a simpler variation of the same methods of user operation and very close to identical wording and packaging design and an identical user demographic base, PSAE believes that no significant differences in those specific characteristics exists between the SL-8813 and the previously approved StarLite-LM device (K092460**).**

Therefore SL-8813 raises no new questions of safety, and an addendum Usability Study was performed to evaluate Self Selection and other considerations for Human Factors – Usability comprehension to assess differences in packaging design and modified indications for use between the SL-8813 and the Secondary Predicate .

9) Table 1 – Applied International Standards

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
IEC 61000-4-3 Ed 3.0 2006-02	Electro Magnetic Compatibility - Testing and measurement techniques – Radiated, radio frequency, electromagnetic field immunity test
CEI/IEC 62304:2006 Ed1 2006-05	Medical Device Software - Software life cycle processes
IEC 61000-4-2 Ed 2.0 2008-12	Electromagnetic Compatibility (EMC) Testing and measurement techniques – Electrostatic discharge immunity test
ANSI/AAMI IEC 60601-2:2007(R) 2012	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and Tests
EN ISO 14791:2012	Medical Devices – Application of risk management to Medical Devices
IEC/TR 62471-2 Ed 1.0 2009-08	Photobiological safety of lamps and lamp systems – Part 2 Guidance on manufacturing requirements relating to non-laser optical radiation safety

10) Clinical Testing

There were no clinical test requirements for this submission. An addendum Usability / Self Selection study was performed.